



1274 '99 MMR 23 P2:14

March 15, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Garlic XTRATM: [It] promotes healthy heart function and cholesterol levels. It has been shown to help promote healthy cholesterol levels, cardiovascular health and circulatory function. Sundown Garlic XTRA features standardized Garlic concentrate (standardized to yield 1% allicin, 2.4 mg per tablet) blended with Hawthorn, Korean Ginseng, Vitamin C and Chromium Picolinate, which work in harmony to help promote healthy heart function and cholesterol levels.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,
Damah Shun Amkr

Deborah Shur Trinker

Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure